ISRCTN41196151 https://doi.org/10.1186/ISRCTN41196151

A randomised controlled trial to assess the efficacy of Laparoscopic Uterosacral Nerve Ablation (LUNA) in the treatment of chronic pelvic pain

Submission date
08/10/2002

Registration date
08/10/2002

Last Edited
03/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
LUNA

Study objectives
1. To test the hypothesis that in women with chronic pelvic pain in whom diagnostic laparoscopy reveals either no pathology or mild endometriosis (American Fertility Society [AFS] score less than or equal to 5) LUNA alleviates pain and improves life quality at 12 months (principal objective)
2. To test the hypothesis that response to LUNA differs according to the site and cause of the pain by two secondary analyses:
2.1. Women with central pain
2.2. Women with no visible pathology
3. To explore the variation in LUNA's effectiveness and side effects at different periods of follow-up (3 and 6 months and 1, 2, 3, 5 and 10 years)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic pelvic pain in women

Interventions

1. Diagnostic laparoscopy plus uterosacral nerve ablation (experimental group)
2. Laparoscopy without pelvic denervation (control group)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
01/09/2005

Eligibility

Key inclusion criteria
New patients presenting to the gynaecology outpatient clinic with pelvic pain (cyclical or non-cyclical) and/or dyspareunia, and requiring diagnostic laparoscopy for evaluation of these conditions, will be invited to participate.

Inclusion criteria:
1. Pelvic pain of longer than 6 month duration
2. Pain located within the true pelvis or between and below the anterior iliac crests
3. Associated functional disability
4. Lack of response to medical treatment
5. Diagnostic laparoscopy planned

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
420

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/2004

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Department of Obstetrics and Gynaecology
Birmingham
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B15 2TG

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
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United Kingdom
B15 2TT
+44 (0)121 414 3344
postmaster@bham.ac.uk

Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Wellbeing (UK) (ref: CF/371)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/12/2003		Yes	No
Results article	results	02/09/2009		Yes	No